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PRESS RELEASE

MEDICAL DEVICE MANUFACTURER PLEADS GUILTY TO HEALTHCARE CRIME; AGREES TO PAY MULTI-MILLION DOLLAR FINE FOR FAILURE TO OBTAIN FDA APPROVAL

United States Attorney Colm F. Connolly announced that NuMED, Inc., a medical device manufacturer headquartered in Hopkinton, New York, and Allen J.Tower, Sr., the president of NuMED, Inc., today pleaded guilty in federal district court in Wilmington, Delaware to distributing medical devices that had not been approved by the United States Food & Drug Administration ("FDA") and agreed to pay a criminal fine in the amount of $2,293,451.

The devices at issue in the case were the "Cheatham Platinum Stent" (the "CP Stent"), a device which was used to create, expand or hold open cardiac and other vessels, and the balloon-in-balloon catheter (the "BIB Catheter"), a device primarily used for stent deployment. In pleading guilty, NuMED, Inc. and Tower admitted that they had not obtained the required pre-market approval and/or pre-market clearance from the FDA before distributing either the CP Stent or the BIB catheter. Despite not having such clearance or approval from the FDA, between 1998 and 2004, NuMED, Inc. and Tower manufactured and shipped in interstate commerce more than 2,800 CP Stents and 5,200 BIB catheters. NuMED, Inc. and Tower made a gross profit of $2,261,777 from sales of the unapproved CP Stents and BIB catheters.

The FDA cleared the BIB Catheter for distribution in 2005, but the CP Stent remains unapproved. As part of the sentence, in addition to payment of the fine, the defendants will pay $2,230,103 to The Johns Hopkins University ("JHU") to fund the JHU-sponsored clinical trial of the CP Stent, one of the devices the defendants illegally distributed. If, as a result of the clinical trial, the FDA approves and/or clears the CP Stent for distribution in the United States, the defendants agreed that, for the first five years following FDA approval of the CP Stent, they will provide the CP Stent at no cost to any health care provider in the United States who requests the device for use in accordance with the CP Stent's approved labeling.

"The FDA is responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices designed for use in humans are safe and effective for their intended uses and are labeled accurately and in compliance with the law," stated U.S. Attorney Connolly. "The FDA cannot do its job in protecting the public if healthcare companies fail to follow the proper procedures before distributing medical devices. Today's guilty plea shows that the federal government is holding the medical device industry strictly accountable for improper conduct."

"The regulatory process involved in approving new medical devices exists for the sole purpose of protecting the public," said Kim Rice, Special Agent in Charge, Washington Field Office, FDA/Office of Criminal Investigations. "The FDA will continue to seek criminal resolutions and stiff sanctions when medical device manufacturers egregiously fail to work within that approval process as they bring new technologies to the market."

The case was investigated by Special Agent Douglas Loveland of the Food and Drug Administration, Office of Criminal Investigations. First Assistant U.S. Attorney David C. Weiss and Assistant U.S. Attorney Beth Moskow-Schnoll prosecuted the case.